22 January 2015

EMA/CHMP/109489/2015
Committee for Medicinal Products for Human Use (CHMP)

Sprycel

Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation

International non-proprietary name: dasatinib

Procedure No. EMEA/H/C/000709/PSUV/0041

Period covered by the PSUR: 28 June 2013 – 27 June 2014

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for Sprycel, the scientific conclusions of PRAC are as follows:

During the use of dasatinib, Stevens-Johnsons Syndrome (SJS), toxic epidermal necrolysis (TEN) and erythema multiforme (EM) were rarely observed. Evidence has been presented including positive de-challenge and re-challenge of severe skin reactions (EM and SJS) with dasatinib, but so far the reports have been rare. Given the rarity of these symptoms, establishment of causality based on a solid number of clinical cases is limited. Nevertheless, toxic skin reactions are expected ADRs reported with other tyrosine kinase inhibitors (TKIs) and it is therefore recommended that section 4.8 of the SmPC of dasatinib is updated to include Steven-Johnson syndrome as a new adverse drug reaction with the frequency “not known”. The Package leaflet is updated accordingly.

Therefore, in view of available data regarding severe skin reactions the PRAC considered that changes to the product information were warranted.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for Sprycel, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance dasatinib is favourable subject to the proposed changes to the product information.

The CHMP recommends that the terms of the Marketing Authorisation should be varied.

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